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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/316,001	05/21/99	KENDALL R	FSC-6

HM12/0329

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EXAMINER	
EWOLDT, G	
ART UNIT	**PAPER NUMBER**
1644	8

DATE MAILED: 03/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/316,001	Applicant(s) Kendall et al.
	Examiner Gerald Ewoldt	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Jan 18, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-18* is/are pending in the application.

Of the above, claim(s) *1-11* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *12-18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5 and 7*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election with traverse of Group II, Claims 12-18 in Paper No. 6, filed 1/18/00, is acknowledged. The traversal is on the grounds that a complete search for either Group I or II would necessarily include the other.

The argument is not found persuasive for the following reasons. In addition to being in separate classes and subclasses, a composition and a method of treatment using said composition require different types of searches; the method of treatment search including different limitations.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 12-18 are being acted upon.

2. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948. Applicant is reminded to change the Brief Description of the Drawings in accordance with these changes

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12, 15-16, and 18 are indefinite in the recitation of "DMG". "DMG" is an ambiguous term with no definition outside the given context. Applicant may obviate this rejection by claiming "dimethylglycine (DMG)".

Claims 12-13 and 15-17 are indefinite in the recitation of "PCE". "PCE" is an ambiguous term with no definition outside the given context. Applicant may obviate this rejection by claiming "*Perna canaliculus* (PCE)".

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 12-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Belkowski, S.M., (1991)

Belkowski teaches the use of a combination of DMG and PCE for the treatment of an inflammatory disease. The freeze-dried ground whole mussel (PCE) was added to the subject's feed while the DMG, as an admixture with water, was injected (see particularly pages 58-62). Injected compositions, however, can still be considered "dietary supplements".

The reference teaching differs from the claimed invention in that it does not teach a composition of DMG and PCE administered together and it does not teach a kit comprising a composition of DMG and PCE.

From the teachings of the reference it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to be motivated to combine the DMG and PCE as taught by Belkowski, in a single mixture for convenience, and to place said mixture in a "kit", comprising nothing more than said mixture in daily dosages, again for convenience.

7. Claims 12-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,026,728, (1991, IDS) in view of Caughey et al. (1983, IDS) or Gibson et al, (1980, IDS) or U.S. Patent No. 4,455,298 (1984).

The '728 patent teaches a DMG admixture with water for the treatment of inflammatory disease (see particularly column 6, paragraph 3).

The reference teaching differs from the claimed invention only in that it does not teach a combination of DMG with PCE or a kit comprising the composition

Caughey et al. teach a freeze-dried ground whole mussel PCE composition for use as a dietary supplement for the treatment of an inflammatory disease (see particularly page 197, Patients and Methods).

Gibson et al. teach a freeze-dried ground whole mussel PCE composition for use as a dietary supplement for the treatment of an inflammatory disease (see particularly page 955, Patients and Methods).

The '298 patent teaches a freeze-dried ground whole mussel PCE composition for use as a dietary supplement for the treatment of an inflammatory disease (see particularly columns 1 and 2).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the anti-inflammatory compound DMG, as taught by Kendall et al. with the anti-inflammatory compound/composition of PCE, as taught by Caughey et al. or Gibson et al. or the '298 patent, in a composition for the treatment of inflammation, and to package said composition as a "kit". One of ordinary skill in the art at the time the invention was made would have been motivated to combine the compounds with similar anti-inflammatory activities in an attempt to produce a composition with enhanced activity and to package said composition as a "kit" for convenience. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06)

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald R. Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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March 27, 2000

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